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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,544	10/26/2000	Evy Lundgren-Akerlund	003300-685	8350

21839 7590 04/23/2002

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POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

PRASAD, SARADA C

ART UNIT PAPER NUMBER

1646

DATE MAILED: 04/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/647,544

Applicant(s)

LUNDGREN-AKERLUND, EVY

Examiner

Sarada C Prasad

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-134 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 31-72, 77-84 and 86-134 is/are objected to.
- 8) ☒ Claim(s) 1-134 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Receipt of Applicants' amendment B in Paper No. 7 (1/7/02) and sequence listing in Paper No. 8 (1/22/02) is acknowledged. Amendment to claims 1, 2, 4, 6, 9, 10, 13, 15, 17, 23, 24, 25, 31, 33, 34, 35, 46, 48, 49, 50, 54, 57, 58, 59, 64, 66, 67, 78, 86, 88, 89, 90, 99, 101, 102, 103, 105, 107, 110, 112, 117, 119, 120, 121, 122, and 127 have been entered. Currently claims 1-34 are pending. Additionally, while amendment B corrected a referencing of SEQ ID Nos. 1, 2, 3, 4 as polypeptide or polynucleotide in the instant claims, a similar incorrect referencing is noted through out the specification. Appropriate correction is required.

Lack of Unity of Invention

This application is a 371 of PCT/SE99/00544 (3/31/1999). For applications filed under 371, PCT Rules for lack of unity apply.

This application contains:

Product claims: claims 1-30, 73-76, 85.

Method claims: claims 31-72, 77-84, 86-134.

While each of the groups is independently subject to restriction, it is noted that the method claims lack recitation of a discrete methods step as well as an identifiable active ingredient. Therefore, the applicant is invited to cancel the current method claims and provide new claims that distinctly claim applicants' invention.

The product claims in this application contain the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept. Under PCT Rule 13.1 the following combinations of claims of different categories are permissible and restriction to one of the following combinations is required. In accordance with 37 CFR 1.499,

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applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The Groups for the product claims are as follows:

Group I: Claims 1-9 drawn to an isolated polynucleotide of SEQ ID NO. 1 encoding a polypeptide of SEQ ID NO. 2, and methods of making the polypeptide.

Group II: Claims 1-9 drawn to an isolated polynucleotide of SEQ ID NO. 3 encoding a polypeptide of SEQ ID NO. 4, and methods of making the polypeptide.

Group III: Claims 10-12 drawn to binding entities having the capability of binding to an integrin subunit of $\alpha 10$ of SEQ ID NO. 2.

Group VI: Claims 10-12 drawn to binding entities having the capability of binding to an integrin subunit of $\alpha 10$ of SEQ ID NO. 4.

Group V: Claims 13-17 drawn to a recombinant or isolated integrin heterodimer comprising a subunit $\alpha 10$ of SEQ ID NO. 2, a beta subunit, and a method of making.

Group VI: Claims 13-17 drawn to a recombinant or isolated integrin heterodimer comprising a subunit $\alpha 10$ of SEQ ID NO. 4, a beta subunit, and a method of making.

Group VII: Claims 18-21 drawn to binding entities having the capacity to bind specifically to isolated heterodimer comprising an integrin subunit $\alpha 10$ of SEQ ID NO. 2, and a beta subunit.

Group VIII: Claims 18-21 drawn to binding entities having the capacity to bind specifically to isolated heterodimer comprising an integrin subunit $\alpha 10$ of SEQ ID NO. 4, and a beta subunit.

Group IX: Claims 22-27 drawn to fragments of integrin subunit $\alpha 10$, and methods of producing them.

Group X: Claims 28-30 drawn to binding entities having the capability of specifically binding to the fragments of human integrin of subunit $\alpha 10$.

Group XI: Claims 73-75, and 85 drawn to a pharmaceutical composition comprising an antibody capable of binding to integrin subunit $\alpha 10$, or a heterodimer of subunit $\alpha 10$ and a beta subunit for stimulating formation of cartilage, bone or blood vessels.

Group XII: Claims 73-75 drawn to a pharmaceutical composition comprising an antibody capable of binding to integrin subunit $\alpha 10$, or a heterodimer of subunit $\alpha 10$ and a beta subunit for inhibiting or blocking the formation of cartilage, bone or blood vessels.

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Group XIII: Claim 76 drawn to a vaccine composition comprising a polypeptide of the integrin heterodimer comprising the subunit $\alpha 10$ and a beta subunit, or a subunit $\alpha 10$ alone as an active ingredient.

Group XIV: Claim 76 drawn to a vaccine composition comprising the DNA encoding the human integrin subunit $\alpha 10$ as an active ingredient.

Group XV: Claim 76 drawn to a vaccine composition comprising the RNA of the human integrin subunit $\alpha 10$ as an active ingredient.

These inventions listed as Groups I-XV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The polynucleotides of SEQ ID No. 1 and SEQ ID No. 3 of inventions in Groups I and II are unrelated each to the other because they each can encode a monomeric polypeptide of either SEQ ID NO. 2 or SEQ ID NO. 4 that can be used independently of the other. Additionally, the claimed binding entities of the polypeptides of monomeric forms of SEQ ID No. 2 and 4 in Groups III and IV are distinct each from the other, and each of them can be used without the need of the other.

Further, Groups V and VI, drawn to recombinant integrin heterodimers comprising the integrin subunit $\alpha 10$ of SEQ ID No. 2 or SEQ ID NO. 4 together with a β subunit are distinct each from the other, and they are also distinct from the monomers of Groups I and II. As in the case of binding entities of monomeric integrin subunits of Groups III and IV, the binding entities having the capacity to bind specifically to isolated heterodimers in Groups VII and VIII are each distinct, and distinct from Groups V and VI that can bind to monomeric integrin subunits.

Again Groups IX and X drawn to fragments of integrin $\alpha 10$ subunits, and the binding entities to such fragments respectively are each distinct and distinct from Groups I-VIII, because

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the binding entities that bind to full length polypeptides (Groups I-VIII, covering polypeptides and their corresponding antibodies), may not bind to fragments of any region of polypeptide of SEQ ID No. 2 or 4 (IX, covered in Groups IX-X).

Furthermore, Groups XI and XII comprising pharmaceutical compositions of antibodies that can bind to and stimulate cartilage, bone or blood vessel formation are distinct from those that can inhibit the formation of cartilage, bone or blood vessels.

Thus the technical feature of each of these inventions I-XII is distinct because they are drawn to different products, used in different methods that produce different results, which are not coextensive, and therefore they do not share the same technical feature.

These inventions of Groups I-XII also do not meet the requirement for Unity of invention for the following reasons: These inventions do not share the special technical feature which defines a contribution which each of these inventions makes over prior art. These polynucleotides, polypeptides and the binding entities and pharmaceutical compositions have patentably distinct uses.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday - Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.
Examiner Art Unit 1646
April 17th, 2002.


YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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